IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Eric Tomasetti et al. Art Unit 1734
Serial No. 10/811,589
Filed March 29, 2004
Confirmation No. 2100
For METHOD FOR STERILE CONNECTION OF TUBING
Examiner Kimberly Kyle McClelland

APPEAL BRIEF

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July 21, 2006

APPEAL BRIEF

This is an appeal from the final rejection of the claims of the above-referenced application made in the final Office action dated January 27, 2006. A Notice of Appeal was filed on May 24, 2006.

The Commissioner is hereby authorized to charge the fee for the appeal brief in the amount of $250 to Deposit Account No. 19-1345. The Commissioner is also hereby authorized to charge any additional fees which may be required to Deposit Account No. 19-1345.

I. REAL PARTY IN INTEREST

The real party in interest Baxter International Inc., a corporation of the State of Delaware and the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

Appellant and appellant's legal representative are unaware of any other appeals or interferences which are related to, which would directly affect, which would be directly affected by, or which would have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-23 are currently pending in this application. Claims 1-23 stand rejected. A copy of the claims on appeal appears in the Claims Appendix of this Brief.

Claims 1-8, 16, and 17 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. App. Pub. No. 2003/0143352 (Yang). Claim 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Yang in view of U.S. Patent No. 5,674,333 (Spencer). Claims 10-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yang in view of Spencer and in further view of U.S. Patent No. 4,832,773 (Shaposka). Claims 18-20 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yang in view of U.S. Patent No. 6,860,960 (Flannagan) and Shaposka. Claim 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over Yang in view of Flannagan and Shaposka and in further view of U.S. Patent No. 5,378,313 to Pace. Claim 23 is rejected under 35 U.S.C. §103(a) as being unpatentable over Yang and Spencer in further view of Shaposka.

The rejections of claims 1-23 are being appealed.

IV. STATUS OF AMENDMENTS

Amendment B was submitted after issuance of the final Office action. The Examiner denied entry of Amendment B.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary correlates claim elements to specific embodiments described in the application specification, but does not in any manner limit claim interpretation. Rather, the following summary is provided only to facilitate the Board's understanding of the subject matter of this appeal.

With reference to the present specification and drawings, claim 1 is directed to a method of connecting together two

sections of tubing. The two tubing sections 1,3 are placed in opposed, end-to-end relation so that axially facing surfaces 31 (Figs. 4A-4B) of the tube sections at the ends are free from exposure to the surrounding environment. Page 13, lines 4-9; Fig. 5. An electromagnetic beam (e.g., from laser 23) is then directed generally toward the location where the axially facing surfaces 31 are in opposed, end-to-end relation to weld the two sections 1, 3 of tubing together at the location. Page 14, lines 18-33; Fig. 5.

Claim 18 is directed to a method of sealing a section of tubing. At least a portion of the tubing section 1 is collapsed (e.g., by clamps 9, 11). Page 9 lines 18-36; Fig. 1. The collapsed portion of the tubing section 1 is placed in contact with an energy absorption member 29. Page 11, lines 2-6; Fig. 2. A beam of electromagnetic energy (e.g., from laser 23) is directed onto the energy absorption member 29. Page 11, lines 2-6; Fig. 2. The energy absorption member 29 is constructed for absorbing energy from the beam. Page 11, lines 10-12. Heat is transferred from the energy absorption member to the collapsed tubing section portion by contact with the energy absorption member to melt and seal the collapsed tubing section portion in its collapsed configuration. Page 11, lines 15-18.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Appellant appeals the rejections of Claims 1-8, 16, and 17 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. App. Pub. No. 2003/0143352 (Yang).

B. Appellant also appeals the rejection of claims 18-20 and 22 under 35 U.S.C. §103(a) as being unpatentable over Yang in view of U.S. Patent No. 6,860,960 (Flannagan) and Shaposka.

VII. ARGUMENT

A. Claims 1-8, 16, and 17 are unanticipated by U.S. Pat. App. Pub. No. 2003/0143352 (Yang).

Claims 1, 3-5, 7, and 17

It is often important to be able to maintain (or possibly establish) aseptic or sterile conditions in polymeric tubing during connection of one piece of tubing to another. For example, there is often a need to connect polymeric tubing to deliver flowable food or medical products (e.g., those used for dialysis treatment). This has been done by cutting the tubing by melting it with a heated wafer or hot knife and then joining two ends together before they cool to melt seal the ends together. However, this type of method is unreliable because variations in the melting and cutting process, sometimes result in imperfect seals, leaks, or bacterial infiltrations. Even if the process works as designed, there is opportunity for contamination because the heated ends of the tubing sections are uncovered and exposed to the surrounding environment in the time between the cutting/melting and joining.

The applicants have solved the foregoing problem with their present invention. Briefly, two tubing sections to be joined are placed in opposed end-to-end relation so that the axially facing surfaces are free from exposure to the surrounding environment. Then an electromagnetic beam (e.g., a laser beam) is used to weld the two tubing sections together. This way the axially facing surfaces of the tubing sections are not exposed to the environment after the heating of the ends of the tubing sections, thereby reducing the opportunity for contamination.

Further, concerns about contamination of the tubing from before the placing of the ends of the tubing sections in opposed end-to-end relation are alleviated because the electromagnetic beam can sanitize (or sterilize) the ends of the tubing sections in the process of welding the tubing sections together.

As indicated by the phrase "and then", claim 1 recites that the steps are carried out in a particular order. First, the tube sections are placed in end-to-end relation so that the axially facing surfaces (i.e., the ends of the tubes) are free from exposure to the environment. Then, a beam of electromagnetic radiation is directed to the location where the ends of the tubes are located to weld the tubes together. In the process of welding the ends of the tubes, the beam kills microbes at the ends of the tubes, thereby allowing the connection to be made aseptic or sterile if need be.

The prior art, including Yang, fails to show or suggest the method of claim 1. In particular, the prior art fails to teach placing two tubing sections in opposed end-to-end relation so the axially facing surfaces thereof are free from exposure to the surrounding environment and then welding the two tubing sections together with an electromagnetic beam.

A reference does not anticipate a claimed invention unless every element of the claim is found therein. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP §2131. Yang does not teach that the ends of two tubing sections can be welded after they are joined together in end-to-end relation. On the contrary, Yang repeatedly teaches that the ends of the tubing are melted by a laser before they are placed in opposed end-to-end relation so the axially facing surfaces are free from exposure to the environment. Yang explains: "As the laser beam strikes the sealed tube ends 51, the heating, **melting** and

aseptic (and/or sterilization) process begins." Yang, ¶ 69 (emphasis added). Further, "As the temperature of the tubing material at the tube ends 51 increases, **the tube ends begin to melt**, flow and reopen." Id. at ¶ 70 (emphasis added). Also, "[o]nce the heat sensors 320 detect that the required aseptic or sterilization temperature level is attained **and sufficient melting of the tube ends has occurred** the laser 200 shuts off." Id. (emphasis added). After melting the tube ends as described above, Yang explains: "At this point, **the now melted** and aseptically heated or sterilized end tubes 51 contact each other. A weld seal W is formed." Id. at ¶ 71 (emphasis added). Thus, Yang is explicit in its teaching that the ends of the tubes are melted before they are placed in opposed end-to-end relation so that the axially facing surfaces are free from exposure to the environment. There is no ambiguity regarding the state of the material at the tube ends. The ends must be sufficiently melted to form a "weld seal" when they are brought together.

The skilled person understands that the ends of the tubing sections are exposed to the environment after the melting until they are joined to one another. Thus, the skilled person recognizes that it is possible that the melted ends of the tubing sections may be contaminated by being exposed to the environment. Further, any such contamination can be incorporated into the spliced tubing section because the axially facing ends of the tubing sections are incorporated into the spliced tubing produced by the method.

Yang does describe an embodiment in which the laser is energized after the tube ends are joined together. Yang ¶ 71. In particular, Yang explains: "In another embodiment, **the laser unit 200 may be energized again.**" Id. (emphasis added). The

Examiner has chosen to ignore the underlined word in making the novelty rejection. However, the use of the word "again" incorporates the immediately preceding description in Yang of the first embodiment, in which the laser is used to heat the tubes ends so they are melted when they are brought together, to describe the initial steps of the second embodiment. In other words, in this embodiment, tube ends are already welded together when the laser is "energized again". The skilled person understands that the purpose of energizing the laser again is to kill microbes that may have been incorporated into the tubing at the weld. There is no basis for concluding that the tube ends welded together by the laser after the ends of the tubes are in end to end relation so that axially facing surfaces of the tubing ends are free from exposure to the surrounding environment. The Examiner has offered no rationale for reading Yang any other way than as set forth above.

Yang is unambiguous in its teaching that the tube ends are melted when they contact each other. Yang describes that the initial heating by the laser is to a temperature sufficient for melting and aseptic and/or sterilization and that when the tube ends are brought together a weld seal is formed. Yang consistently uses the conjunction "and" rather than "or" to link melting to other results of the heating. See Yang ¶¶ 69-71. Whether or not it would be possible to sterilize the tube ends without melting them is not relevant, because prior art does not anticipate a claim unless it contains each and every element of the claim. *Richardson v. Suzuki* Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989); MPEP § 2131.

Claims 2-17 depend directly or indirectly from claim 1 and are patentable for the same reasons as claim 1.

Claim 2

Claim 2 depends from claim 1 and is unanticipated by Yang for the same reasons as claim 1. Claim 2 further specifies that the temperature of each of the tubing sections at the axial surfaces thereof is below the melting temperature when the tubing sections are placed in end to end relation so that the axially facing surfaces are free from exposure to the environment. As noted above in connection with claim 1, Yang is explicit that the ends of the tubing sections are melted when they are placed together in end to end relation: "At this point, **the now melted** and aseptically heated or sterilized end tubes 51 contact each other. A weld seal W is formed." Yang ¶ 71. (emphasis added). Thus, claim 2 is unanticipated by Yang for the additional reason that Yang does not disclose a method of connecting tubing sections in which the temperature of each of the tubing sections at the axial surfaces thereof is below the melting temperature when the tubing sections are placed in end to end relation so that the axially facing surfaces are free from exposure to the environment. *See Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP §2131.

Claims 6 and 16

Claim 16 depends directly from claim 1, while claim 6 depends indirectly from claim 1 via dependency on dependent claim 3. Accordingly, claims 6 and 16 are both unanticipated by Yang for the same reasons as claim 1.

Claims 6 and 16 each specify that the method includes the step of moving the tubing sections toward each other after they have been heated by the electromagnetic beam causing some of the material of the tubing sections to flow radially outwardly. The movement step must also occur after the tubing sections have

been brought together. This step may be desirable because it can facilitate establishing fluid communication between the tubing sections after the weld is formed. See specification ¶43.

The method disclosed in Yang fails to include a step of moving the tubing sections toward each other after they have been brought together and heated by an electromagnetic beam causing some of the material of the tubing sections to flow radially outwardly. Instead, Yang teaches that the sealed end of a tube section peels open and flares outward spontaneously upon application of the laser thereto because of "memory" of the tubing material. See Yang ¶70; Figs. 5A-5C. Thus, the movement of material of the tubing sections radially outwardly discussed in Yang has nothing to with movement of the tubing sections toward each other. Accordingly, claims 6 and 16 are unanticipated by Yang for the additional reason that Yang fails to disclose a step of moving the tubing sections toward each other after they have been brought together and heated by an electromagnetic beam causing some of the material of the tubing sections to flow radially outwardly. *See Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP §2131.

B. Claims 18-20 and 22 are patentable over Yang in view of U.S. Patent No. 6,860,960 (Flannagan) and U.S. Patent No. 4,937,880 (Shaposka).

Claims 18-20 and 22

Claim 18 is directed to a method of sealing a section of tubing. The method includes collapsing at least a portion of the tubing section, placing the collapsed portion in contact with an energy absorption member, directing electromagnetic radiation onto the energy absorption member, and transferring heat from the energy absorption member to the collapsed tubing section to

seal the collapsed tubing section in its collapsed configuration.

Yang discloses a method of sealing a tubing section by placing the end of the tubing section against an energy absorption member and directing electromagnetic radiation onto the energy absorption member. Heat is transferred to the tubing section to seal the tubing section. Yang does not address sealing a tubing section in its collapsed condition. Instead, Yang teaches that the guides 56, 58 (Fig. 4B) crimp or squish the tubing and advance each end of tubing into the device to purge fluid from the tubing. ¶67. It is evident that the tubing expands from its collapsed configuration as it advances past the guides so that the ends of the tubing are not in their collapsed configuration when they are sealed.

Flannagan also fails to show or suggest the method of claim 18. Flannagan is directed to a method of bonding a polymeric material to a catheter tube using an electromagnetic beam (e.g., laser) to melt the materials to form a fusion bond. Rather than an energy absorption member, Flannagan teaches that melting is achieved by suitably focusing the electromagnetic radiation and/or by using a wavelength that is strongly absorbed by one or both materials.

An obviousness rejection requires some suggestion or motivation in the reference to make the modification. *In re Mills*, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990); MPEP § 2143.01. The Shaposka '880 patent explains that flattening (e.g., collapsing) tubing builds up large stresses in the tube that make it difficult to produce a reliable, sterile seal during welding of the tubing. Col. 1, lines 24-30. The skilled person recognizes that a primary focus of the Shaposka '880 patent is on alleviating problems associated with the stresses

caused by flattening the tubing sections. Accordingly, the Shaposka '880 patent provides no motivation for the skilled person to modify a Yang so that a tubing section that is sealed in its uncollapsed condition by the prior art system is instead sealed in its collapsed condition. The alleged motivation of excluding fluid from the tubing section does not withstand scrutiny because the Yang system already has a system for purging the tubing sections of fluid.

Claim 18 is patentable over Yang, Flannagan, and Shaposka because there is no motivation to modify the Yang system as proposed in the rejection. Claims 19-23 depend from claim 18 and are patentable for the same reason.

VIII. CONCLUSION

For the reasons stated above, appellants respectfully request that the Office's rejections be reversed and that claims 1-14 and 16-23 be allowed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A method of connecting together two sections of tubing comprising the steps of:

placing the two tubing sections in opposed, end-to-end relation so that axially facing surfaces of the tube sections at the ends are free from exposure to the surrounding environment; and then

directing an electromagnetic beam generally toward the location where the axially facing surfaces are in opposed, end-to-end relation for welding the two sections of tubing together at the location.

2. A method as set forth in claim 1 wherein during the step of placing the two tubing sections in opposed, end-to-end relation, the temperature of each of the tubing sections at the axial surfaces thereof is below the melting temperature of material forming the tubing section.

3. A method as set forth in claim 1 further comprising providing material for absorbing energy from the electromagnetic beam at the ends of the tubing sections where connection is to occur for use in fusing the tubing sections together.

4. A method as set forth in claim 3 wherein said step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces at the ends of

the tubing sections, the sheet being formed of a material which absorbs the energy of the electromagnetic beam.

5. A method as set forth in claim 4 wherein the tubing sections are formed of a material which is substantially transparent to the electromagnetic beam.

6. A method as set forth in claim 3 further comprising, following the step of directing an electromagnetic beam, the step of moving the tubing sections toward each other causing some material of the tubing sections to flow radially outwardly.

7. A method as set forth in claim 3 wherein the step of providing an absorbing material comprises applying a dye to the axially facing surface of at least one of the tubing sections, the dye being selected to increase absorption of energy from the electromagnetic beam to promote fusion of the tubing sections at the axially facing surfaces.

8. A method as set forth in claim 7 wherein the step of placing the two tubing sections in opposed, end-to-end relation includes bringing the axially facing surfaces of the tubing sections into engagement with each other.

9. A method as set forth in claim 3 further comprising, prior to the step of placing the two tubing sections in opposed, end-to-end relation, the step of positioning the two

tubing sections in substantially coaxial position and cutting off end portions of the tubing sections.

10. A method as set forth in claim 9 further comprising clamping cut end margins of the two tubing sections closed.

11. A method as set forth in claim 10 further comprising welding each of the closed cut end margins to seal interior passages of the tubing section.

12. A method as set forth in claim 11 wherein the step of welding each of the closed cut end margins comprises directing a beam of electromagnetic radiation onto a block in contact with the closed cut end margin, the block absorbing energy from the electromagnetic beam and transferring heat to the tubing section with which it is in contact.

13. A method as set forth in claim 11 further comprising, following the step of directing an electromagnetic beam, the step of reopening the closed end margins of the joined tubing sections by squeezing the tubing sections.

14. A method as set forth in claim 13 further comprising, following the step of directing an electromagnetic beam and prior to the step of reopening the closed end margins, the step of shipping the connected tubing sections to a remote location.

15. A method as set forth in claim 11 wherein all of the steps are carried out with the tubing sections in said substantially coaxial position.

16. A method as set forth in claim 1 further comprising, following the step of directing an electromagnetic beam, the step of moving the tubing sections toward each other causing some material of the tubing sections to flow radially outwardly.

17. A method as set forth in claim 1 wherein the step of directing an electromagnetic beam comprises directing a laser beam toward the location where the axially facing surfaces are in opposed, end-to-end relation.

18. A method of sealing a section of tubing comprising:

collapsing at least a portion of the tubing section;

placing the collapsed portion of the tubing section in contact with an energy absorption member;

directing a beam of electromagnetic energy onto the energy absorption member, the energy absorption member being constructed for absorbing energy from the beam; and

transferring heat from the energy absorption member to the collapsed tubing section portion by contact therewith to melt and seal the collapsed tubing section portion in its collapsed configuration.

19. A method as set forth in claim 18 wherein the energy absorption member has low thermal conductivity.

20. A method as set forth in claim 19 wherein the energy absorption member comprises a block.

21. A method as set forth in claim 20 wherein the block is made of one of polytetrafluoroethylene and glass.

22. A method as set forth in claim 18 wherein the energy absorption member comprises a film.

23. A method as set forth in claim 13 wherein said step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces at the ends of the tubing section, the sheet being capable of absorbing the energy of the electromagnetic beam.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.